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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/943,776	10/03/1997	MARIAPIA A. DEGLI-ESPOSTI	2849-A	9687

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/943,776	DEGLI-ESPOSTI ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,7,10,11,13,14,16 and 20-32* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,7,10,11,13,14,16 and 22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3,6,7,10,11,13,14,16,20-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/9/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Part III: Detailed Office Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/2004 has been entered.

The amendment received 12/8/2003 has been entered.

Claims 1, 3, 6, 7, 10, 11, 13-14, 16 and 33-43 are under consideration.

Formal Matters:

The listing of claims submitted 12/8/2003 is not consistent with the file history. Claims 20 and 21 are listed as 'currently amended' and 'original' respectively, however, the record shows that both claims are cancelled. However, the Examiner can locate no instruction on the record to cancel the claims. Clarification is required regarding whether the claims are pending, and on what date they were cancelled, if such is not the case. *If* the claims have been cancelled, a new listing of the claims is required in response to this office action.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 7, 11, 14 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 3 and 26 have been amended to recite "98% identical". Applicants point to page 9, which recites that peptides at least about 90% identical for basis for the new

limitation. This argument has been fully considered but is not deemed persuasive because a recitation of "at least about 90%" does not provide basis for "98% identical". New recitation of a single member of a range is new matter, as the specification evidences no contemplation of that particular limitation.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fragments of SEQ ID NO: 2 having apoptotic activity, does not reasonably provide enablement for any/all possible fragments of SEQ ID NO: 2 and fusions thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The newly introduced claims include "a fragment thereof" without regard to conserved structure or function. The specification does not breath life and meaning into the term "fragment" as it is drawn to protein. Given its broadest reasonable interpretation, a "fragment" could be as little as two amino acids. The vast majority of species encompassed by the claims will lack the activity disclosed for SEQ ID NO: 2, that of being able to induce apoptosis. The specification has not taught how to use such species. Accordingly, enablement is not commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-14 are indefinite because they read on expression of *any* protein that might be produced by the host cell (e.g. DNA polymerase) and have no limitation specific to the protein encoded by the claimed DNA sequences. Accordingly, the claims fail to adequately point out what applicant regards as the invention.

Claims 31-32 are indefinite for failing to adequately point out that which applicant regards as the invention. Claim 31 recites "or a fragment thereof", without specifying any function or minimum fragment size. Accordingly, the claim would read on any protien with an extracellular domain that shared in common at least two contiguous amino acids of SEQ ID NO: 2. As that would be a very large number of proteins that share neither significant structural features nor function, the claim does not adequately point out what the invention is. Claim 32 is rejected for depending from claim 31.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 7, 11, 14, 22-28 and 31-32 are/remain rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al., U.S. Patent Number 6,153,402, for reasons of record in the previous Office Action, paper number 13. With respect to fusion proteins, see column 16 and claims 55-56. With respect to variants, see column 12, wherein it is stated that the invention includes nucleic acids 90% identical which encode functional proteins, and columns 17-20, which disclose polypeptide variants.

Claims 1, 3, 6, 7, 10, 11, 13-14, 16 and 33-43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 6,462,176 and US Patent Application Publication US2002/0192729 A1 (Ashkenazi-1 and –2), both cited by applicants.

Ashkenazi-1 and –2 both disclose Apo-3 protein, which is 100% identical to SEQ ID NO: 2 of the instant application, see SEQ ID NO: 10 of the '176 patent. The '176 patent also discloses and claims fragments and Ig fusions. See also claims 19-39 of Ashkenazi-2. Both documents merit priority to 9/23/1996, one and one-half weeks prior to the earliest priority date.

Applicants are reminded that in order to provoke an interference, applicants must file a statement in accordance with 37 C.F.R. § 1.608(a), see MPEP 2308.01.

Advisory Information:

Claims 1, 6, 10, 16, 29 and 30 are allowable.

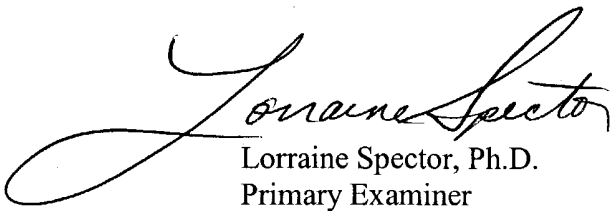
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. ***Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.***

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner